



DOCKET NO.: TJU-2444

1642
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Confirmation No.: 8378

Application No.: 09/724,983

Group Art Unit: 1642

Filing Date: November 28, 2000

Examiner: Gary B. Nickol

For: **ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING THE SAME**

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DATE OF DEPOSIT:

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Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

**COMMUNICATION REGARDING
INFORMATION DISCLOSURE STATEMENT**

- ☒ In the Office Action dated December 31, 2002, the Examiner indicated that certain references were not considered; the Examiner has requested additional copies of references that were previously cited by or submitted to the Patent and Trademark Office. Enclosed are copies of references AA-GH (with the exception of AB, AE, AK and BY which are voluminous and CO which is a duplicate of CN) that were listed on the PTO Form 1449 originally filed May 15, 2001, a copy of which is attached to this communication. A copy of the date-stamped postcard dated May 17, 2001 is also attached. Accordingly, Applicants believe no fee is due for providing copies of these references.

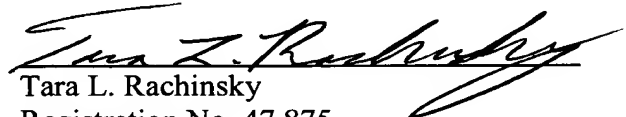
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- ☒ It is respectfully requested that the Examiner initial and date the attached pages of the 1449 confirming that the references citing thereon have been considered. A clean copy of the PTO-1449 is enclosed for the Examiner's convenience.

The Commissioner is authorized to charge payment of any fees associated with this communication and to refund any overpayment associated with this communication or during the pendency of this application to deposit account 23-3050.

Date: *July 24, 2003*


Tara L. Rachinsky
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Paper: Information Disclosure Statement (in duplicate) w/ first class stamp; USPTO-1449 (13 pages); 164 references cited/ 1 reference submitted; return postcard

Applicant(s) : Scott A. Waldman

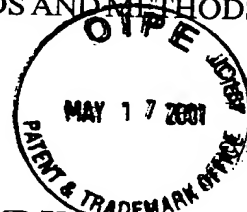
Title: STRECEPTOR BINDING COMPOUNDS AND METHODS OF USING THE SAME

Serial No.: 09/724,983

Filed: November 28, 2000

Docket No.: TJU-2444

Date Sent: May 15, 2001



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DOCKET NO.: TJU-2444

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Serial No.: 09/724,983

Group Art Unit: Not Yet Assigned

Filing Date: November 28, 2000

Examiner: Not Yet Assigned

For: ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING
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TYPED NAME: Mark DeLuca
REGISTRATION NO.: 33,229

Assistant Commissioner for Patents
Washington DC 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).



In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required, or before the mailing date of a first office action after the filing of request for continued examination under §1.114.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
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- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☒ In view of the voluminous nature of references **AB, AK, and BY**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.



In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:



Copies of references **AA, BU, CC, CN, EA-ET, FM-GG** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/583,447**, filed **January 5, 1996**; copies of references **AH-AJ, AL-BT, BV-BX, CA-CB, CD-CM, CO-CS, DJ-DZ, EU-EY, FE-FF and FH-FL** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/635,930**, filed **April 26, 1996**; copies of references **BZ, CT-DI, and EZ-FD** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/468,449**, filed **June 6, 1995**; copies of references **AC-AG** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **09/138,237**, filed **August 21, 1998**.



If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

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- 4 -

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Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: 5 - 15 - 01



Mark DeLuca

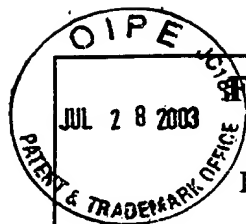
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Form PTO-1449 Modified U.S. Department of Commerce Patent and Trademark Office (Use several sheets if necessary)		Docket No. TJU-2444	Serial No. 09,724,983
		Applicant Scott A. Waldman	
		Filing Date November 28, 2000	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AA	Bremer, K.H., et al., "Safety and efficacy of radiopharmaceuticals," Kristensen, K., et al. (eds.), Martinus Nijhoff, Dordrecht, the Netherlands, 1987, 43-50	
*	AB	Dayhof, <i>Nat. Biomed. Res. Found.</i> , 1978, Washington, D.C., 5, Supp. 3	
	AC	Hugues, M., et al., "Affinity purification of functional receptors for escherichia coli heat-stable enterotoxin from rat intestine," <i>Biochemistry</i> , 1992, 31, 12-16	
	AD	Kent, and Clark-Lewis in Synthetic peptides in biology and medicine, Alitalo, K., et al., (eds.), <i>Science Publishers, Amsterdam</i> , 1985, 295-358	
	AE	The Proteins, Vol. II, 3 rd Ed., pages 105-237, Neurath, H., et al. (eds.), <i>Academic press, New York, NY</i> , 1976	
	AF	Paxton, R.J., et al., "High-specific-activity 111 ^{In} -labeled anticarcinoembryonic antigen monoclonal antibody: improved method for the synthesis of diethylenetriaminepentaacetic acid conjugates," <i>Cancer Res.</i> , 1985, 45, 5694-5699	
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EXAMINER		DATE CONSIDERED	

* A copy of this reference will not be forwarded to the Patent Office since it is believed to be too voluminous to send and easily obtainable by the Examiner.

**Form PTO-1449 Modified**

List of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce
Patent and Trademark Office

Docket No.
TJU-2444

Serial No.
09,724,981

Applicant
Scott A. Waldmann

Filing Date
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AM	Cawley, et al., "Epidermal growth factor-toxin a chain conjugates: EGF-ricin A is a potent toxin while EGF-diphtheria fragment A is nontoxic," <i>Cell</i> , 1980, 22, 563-570
AN	Chan, et al., "Amino acid sequence of heat-stable enterotoxin produced by <i>escherichia coli</i> pathogenic for man," <i>J. Biol. Chem.</i> , 1981, 256, 7744-7746
AO	Chung, et al., "Enzymatically active peptide from the adenosine diphosphate-ribosylating toxin of <i>pseudomonas aeruginosa</i> ," <i>Infection and Immunity</i> , 1977, 16, 832-841
AP	Cumber, et al., "Preparation of antibody-toxin conjugates," <i>Methods in enzymology</i> , 1985, 112, 207-225
AQ	Currie, et al., "Guanylin: an endogenous activator of intestinal guanylate cyclase," <i>Proc. Natl. Acad. Sci. USA</i> , 1992, 89, 947-951
AR	Dreyfus, et al., "Chemical properties of heat-stable enterotoxins produced by enterotoxigenic <i>escherichia coli</i> of different host origins," <i>Infection and Immunity</i> , 1983, 42, 539-548
AS	Eckelman, et al., "Comparison of ^{99m} Tc and ¹¹¹ in labeling of conjugated antibodies," <i>Nucl. Med. Biol.</i> , 1986, 13, 335-343
AT	Evans, et al., "Differences in the response of rabbit small intestine to heat-labile and heat-stable enterotoxins of <i>escherichia coli</i> ," <i>Infection and Immunity</i> , 1973, 7, 873-880
AU	Fitzgerald, et al., "Adenovirus-induced release of epidermal growth factor and <i>pseudomonas</i> toxin into the cytosol of KB cells during receptor-mediated endocytosis," <i>Cell</i> , 1983, 32, 607-617
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U.S. Department of Commerce
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Docket No.
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Serial No.
09,724,983

Applicant
Scott A. Waldmann

Filing Date
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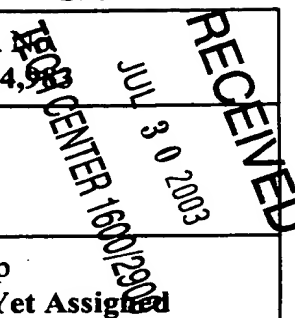
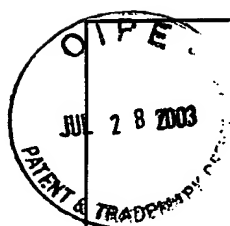
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AX	Gros, O., "Biochemical aspects of immunotoxin preparation," <i>J. Immunol. Meth.</i> , 1985, 81, 283-297
AY	Gyles, C.F., "Discussion: heat-labile and heat-stable forms of the enterotoxin from E. coli strains enteropathogenic for pigs," <i>Ann. N.Y. Acad. Sci.</i> , 1979, 16, 314-321
AZ	Hakki, et al., "Solubilization and characterization of functionally coupled escherichia coli heat-stable toxin receptors and particulate guanylate cyclase associated with the cytoskeleton compartment of intestinal membranes," <i>Int. J. Biochem.</i> , 1993, 25, 557-566
BA	Hugues, et al., "Identification and characterization of a new family of high-affinity receptors for escherichia coli heat-stable enterotoxin in rat intestinal membranes," <i>Biochemistry</i> , 1991, 30, 10738-10745
BB	Humm, et al., "Dosimetric aspects of radiolabeled antibodies for tumor therapy", <i>J. Nuclear Med.</i> , 1986, 27, 1490-1497
BC	Klipstein, et al., "Development of a vaccine of cross-linked heat-stable and heat-labile enterotoxins that protects against escherichia coli producing either enterotoxin", <i>Infection and Immunity</i> , 1982, 37, 550-557
BD	Krejcarek, et al., "Covalent attachment of chelating groups to macromolecules", <i>Biochem. And Biophys. Res. Commun.</i> , 1977, 77, 581-585
BE	Kwok, "Calculation of radiation doses for nonuniformly distributed β and γ radionuclides in soft tissue", <i>Med. Phys.</i> , 1985, 12, 405-412
BF	Leonard, et al., "Kinetics of protein synthesis inactivation in human T-lymphocytes by selective monoclonal antibody-ricin conjugates", <i>Cancer Res.</i> , 1985, 45, 5263-5269
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EXAMINER**DATE CONSIDERED**

Form PTO-1449 ModifiedDocket No.
TJU-2444Serial
09,724,943List of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)Applicant
Scott A. WaldmannU.S. Department of Commerce
Patent and Trademark OfficeFiling Date
November 28, 2000Group
Not Yet Assigned**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

BH	Masuho, et al., "Importance of the antigen-binding valency and the nature of the cross-linking bond in ricin a-chain conjugates with antibody," <i>J. Biochem.</i> , 1982 , 91, 1583-1591
BI	Merrifield, "Solid phase peptide synthesis, I. The synthesis of a tetrapeptide," <i>J. Am. Chem. Society</i> , 1963 , 15, 2149-2154
BJ	Michel, et al., "Fluorescence studies of nucleotides binding to diphtheria toxin and its fragment A," <i>Biochimica et Biophysica Acta</i> , 1974 , 365, 15-27
BK	Moseley, et al., "Isolation and nucleotide sequence determination of a gene encoding a heat-stable enterotoxin of escherichia coli," <i>Infect. And Immun.</i> , 1983 , 39, 1167-1174
BL	Okamoto, et al., "Substitutions of cysteine residues of escherichia coli heat-stable enterotoxin by oligonucleotide-directed mutagenesis," <i>Infect. And Immun.</i> , 1987 , 55, 2121-2125
BM	Richardson, et al., "Astatine (²¹¹ At) as a therapeutic radionuclide. The plasma: blood cell distribution in vitro," <i>Nucl. Med. Biol.</i> , 1986 , 13, 583-584
BN	Sack, "Human diarrheal disease caused by enterotoxigenic escherichia coli," <i>Ann. Rev. Microbiol.</i> , 1975 , 29, 333-353
BO	Shimonishi, et al., "Mode of disulfide bond formation of a heat-stable enterotoxin (St _h) produced by a human strain of enterotoxigenic escherichia coli," <i>FEBS</i> , 1987 , 215, 165-170
BP	So, et al., "Nucleotide sequence of the bacterial transposon Tn1681 encoding a heat-stable (ST) toxin and its identification in enterotoxigenic escherichia coli strains," <i>Proc. Natl. Acad. Sci.</i> , 1980 , 77, 4011-4015
BQ	Spitler, et al., "Therapy of patients with malignant melanoma using a monoclonal antimelanoma antibody-ricin A chain immunotoxin," <i>Cancer Res.</i> , 1987 , 1717-1723
BR	Steinsträßer, et al., "Selection of nuclides for immunoscintigraphy/immunotherapy," <i>J. Nucl. Med.</i> , 1988 , 5, 875
BS	Thompson, et al., "Biological and immunological characteristics of ¹²⁵ I try escherichia coli heat-stable enterotoxin species purified by high-performance liquid chromatography," <i>Analytical Biochem.</i> , 1985 , 26-36

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2444	Serial No. 09,724,883
		Applicant Scott A. Waldmann	
		Filing Date November 28, 2000	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	BT	Thorpe, et al., "New coupling agents for the synthesis of immunotoxins containing a hindered disulfide bond with improved stability in vivo," <i>Cancer Research</i> , 1987, 47, 5924-5931	
	BU	Waldman, et al., "Influence of a glycine or proline substitution on the functional properties of a 14-amino-acid analog of escherichia coli heat-stable enterotoxin," <i>Infect. And Immun.</i> , 1989, 57, 2420-2424	
	BV	Wessels, et al., "Radionuclide selection and model absorbed dose calculations for radiolabeled tumor associated antibodies," <i>Med. Phys.</i> , 1984, 11, 638-645	
	BW	Worrell, et al., "Effect of linkage variation on pharmacokinetics of ricin A chain-antibody conjugates in normal rats," <i>Anti-Cancer Drug Design</i> , 1986, 1, 179-188	
	BX	Yoshimura, et al., "Essential structure for full enterotoxigenic activity of heat-stable enterotoxin produced by enterotoxigenic escherichia coli," <i>FEBS</i> , 1985, 2232, Vol. 181, 138-142	
*	BY	Barchel, et al., "Radioimaging and radiotherapy," New York, 1983	
	BZ	Farnz, et al., "The production of ^{99m} Tc-labeled conjugated antibodies using a cyclam-based bifunctional chelating agent," <i>J. Nucl. Med. Biol.</i> , 1987, 14, 569-572	
	CA	de Sauvage, F., et al., "Primary structure and functional expression of the human receptor for escherichia coli heat-stable enterotoxin," <i>J. Bio. Chem.</i> , 1991, 266, 17912-17918	
	CB	Corstens, et al., "Chemotactic peptides: new locomotion for imaging infection?," <i>J. Nucl. Med.</i> , 1991, 32(3), 491-494	
	CC	Fischman, et al., "A ticket to ride: peptide radiopharmaceuticals," <i>J. Nucl. Med.</i> , 1993, 34, 2253-2263	
	CD	Thompson, "Escherichia coli heat-stable enterotoxins and their receptors," <i>Pathol. Immunopathol. Res.</i> , 1987, 6, 103-116	
	CE	Cohen, M., et al., "Receptors for escherichia coli heat stable enterotoxin in human intestine and in a human intestinal cell line (Caco-2)," <i>J. Cellular Physiol.</i> , 1993, 156, 138-144	

* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.


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List of Patent and Publications
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Applicant
Scott A. Waldmann

Filing Date
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Group
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	CF	Guarino, A., et al., "T ⁸⁴ cell receptor binding and guanyl cyclase activation by escherichia coli heat-stable toxin," <i>Am. J. Physiol.</i> , 1987 , <i>253</i> , (Gastrointest. Liver Physiol. 16): G775-780
	CG	Vaandrager, A., et al., "Atriopeptins and escherichia coli enterotoxin ST ^a have different sites of action in mammalian intestine," <i>Gastroenterology</i> , 1992 , <i>102</i> (4), 1161-1169
	CH	Aitken, R. et al., "Recombinant enterotoxins as vaccines against <i>Escherichia coli</i> -mediated diarrhoea", <i>Vaccine</i> , 1993 , <i>11</i> (2), 227-233
	CI	Chelly, J. et al., "Illegitimate transcription: Transcription of any gene in any cell type", <i>Proc. Natl. Acad. Sci. USA</i> , 1989 , <i>86</i> , 2617-2621
	CJ	Chelly, J. et al., "Illegitimate Transcription: Application to the Analysis of Truncated Transcripts of the Dystrophin Gene in Nonmuscle Cultured Cells from Duchenne and Becker Patients", <i>J. Clin. Invest.</i> , 1991 , <i>88</i> (4), 1161-1166
	CK	Cooper, D.N. et al., "Ectopic (Illegitimate) Transcription: New Possibilities for the Analysis and Diagnosis of Human Genetic Disease", <i>Ann. Med.</i> , 1994 , <i>26</i> (1), 9-14
	CL	Field, M., "Role of Cyclic Nucleotides in Enterotoxic Diarrhea", <i>Mol. Cyclic Nucl. Res.</i> , 1980 , <i>12</i> , 267-277
	CM	Giannella, R.A., "Pathogenesis of Acute Bacterial Diarrheal Disorders", <i>Ann. Rev. Med.</i> , 1981 , <i>32</i> , 341-357
	CN	Kaplan, J.C. et al., "Illegitimate transcription: its use in the study of inherited disease", <i>Human Mutation</i> , 1992 , <i>1</i> (5), 357-360 (Abstract only)
<i>Copy of CN</i>	CO	Kaplan, J.C. et al., "Illegitimate transcription: its use in the study of inherited disease", <i>Human Mutation</i> , 1992 , <i>1</i> (5), 357-360 (Abstract only)
	CP	Negrier, C. et al., "Illegitimate transcription: its use for studying genetic abnormalities in lymphoblastoid cells from patients with Glanzmann thrombasthenia", <i>British J. Haematology</i> , 1998 , <i>100</i> (1), 33-39

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2444	Serial No. 09,724,283
		Applicant Scott A. Waldmann	
		Filing Date November 28, 2000	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	CQ	Rao, M.C. et al., "Enterotoxins and Anti-toxins: Enterotoxins and ion transport", <i>Biochem.</i> , 1984 , <i>12</i> , 177-180	
	CR	Zippelius, A. et al., "Limitations of Reverse-Transcriptase Polymerase Chain Reaction Analyses for Detection of Micrometastatic Epithelial Cancer Cells in Bone Marrow", <i>J. Clin. Oncology</i> , 1997 , <i>15</i> (7), 2701-2708	
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	CT	Aimoto, S., et al., "Chemical synthesis of a highly potent and heat-stable analog of an enterotoxin produced by a human strain of enterotoxigenic escherichia coli," <i>Biochem. & Biophys. Res. Comm.</i> , 1983 , <i>112</i> (1), 320-326	
	CU	Carepick, B.W., et al., "The escherichia coli heat-stable enterotoxin is a long-lived superagonist of guanylin," <i>Infection & Immunity</i> , 1993 , <i>61</i> (11), 4710-4715	
	CV	Garipey, J., "Importance of disulfide bridges in the structure and activity of escherichia coli enterotoxin St1b," <i>Proc. Natl. Acad. Sci. USA</i> , 1987 , <i>84</i> , 8907-8911	
	CW	Hamra, F.K., et al., "Uroguanylin: structure and activity of a second endogenous peptide that stimulates intestinal guanylate cyclase," <i>Proc. Natl. Acad. Sci. USA</i> , 1993 , <i>90</i> , 10464-10468	
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Docket No.
TJU-2444

Serial No.
09,724,983

Applicant
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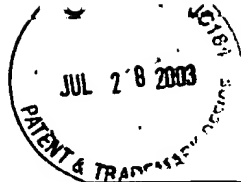
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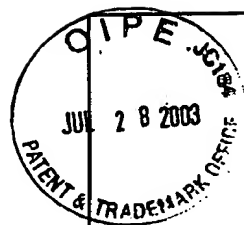
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